K010807

AUG - 9 2001

# 510(k) SUMMARY
# SA-100
# March 12th,2001

1. Applicant, Official Correspondent and Owner of 510 (k)

Health@fitness Technologies Inc.
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21000 Split
Croatia

Attn: Mr.Ivan Vrdoljak, PhD, President, Research and Development
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Submitter of 510(k)
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2. Name of Device

Trade/Proprietary Name: Muscle Stimulator SA-100
Common/Usual Name: Muscle Stimulator
Classification Name: Physical Medicine 21 CFR 890.5850 "Powered Muscle Stimulator", Class II.

3. Legally Marketed Predicate Device

The SA-100 is substantially equivalent to legally marketed device RS-4M+ (K000114) muscle stimulator and RS-4V (K990697) muscle stimulator.

4. Indications for Use
   Muscle Stimulation
   - Relax muscle spasms
   - Prevent or retard disuse atrophy
   - Maintain or increase range of motion
   - Increase local blood circulation
   - Re-educate muscle
   - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

5. Device Description and Substantial Equivalence

The SA-100, like a number of legally marketed predicate devices, incorporates muscle stimulation functions into one device. The SA-100 operates only one function at a time. The SA-100 is embedded in a plastic enclosure. The enclosure has two hardware interfaces. One interface is an interface to Personal Computer parallel port. To the other interface are connected output cables.
The enclosure has toggle switch for on-off switching of the device. LED indicator on the enclosure indicates that battery provides needed level of voltage for the normal usage of the device. All control functions of the SA-100 are realised on Personal Computer while SA-100 is connected to a Personal Computer's parallel port. Desired/prescribed signal characteristics are downloaded from Personal Computer to SA-100 that stores defined signal parameters and generates appropriate waveforms of electric signals. The accessories provided with the SA-100 include the output cables and the electrode pads.

The SA-100 operates in muscle stimulation modality at a 20 volts peak (+/-5% into a 500 ohm load) and 40 mA peak (+/-5% into a 500 ohm lead) with a pulse width of 50-400 uSec (maximum +/- 5%) and a cycle frequency of 40-150 Hz (+/-5%). The pulses are bi-phasic.
For safety of the patient output voltage is limited to 60V by Zehner diode at the each output channel of the SA-100.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2001

Ivan Vrdoljak, Ph.D.
President
Health@Fitness Technologies, Inc.
Karamanova 11
21000 Split
Croatia

Re: K010807
Trade/Device Name: Muscle Stimulator SA-100
Regulation Number: 890.5850
Regulatory Class: II
Product Code: IPF
Dated: June 27, 2001
Received: June 27, 2001

Dear Dr. Vrdoljak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 14. Indications for Use



510(k) Number (if known): K010807

SA-100

Device Name: _____

Indications for Use:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

for Mark N. Milhauser

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010807